DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 1, 2015

APEX BIOTECHNOLOGY CORP.
HSUE-MEI LEE, MANAGER OF QUALITY ASSURANCE DEPT.
NO. 7, LI-HSIN ROAD V,
HSINCHU SCIENCE PARK
HSINCHU 30078, TAIWAN

Re: K141036
Trade/Device Name: BGM009 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: April 22, 2015
Received: April 23, 2015

Dear Hsue-mei Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k141036

Device Name
BGM009 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The BGM009 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). The device includes speaking functions but is not intended for use in visually impaired users. It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

The BGM009 Blood Glucose Test Strips are to be used with the BGM009 Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
Contact Person:	Hsue-mei Lee Manager of Quality Assurance Department Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Date Prepared:	Septebmer 10, 2014
Trade Names:	BGM009 Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW
Predicate Devices:	AutoSure Voice II Plus Blood Glucose Monitoring System (k113208)
Device Description:	The BGM009 blood glucose meter and BGM009 test strips are used for testing of blood glucose.

Intended Use:	The BGM009 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. ***Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).*** The device includes speaking functions but is not intended for use in visually impaired users. It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. The BGM009 Blood Glucose Test Strips are to be used with the BGM009 Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.
Comparison of Technological Characteristics:	The BGM009 meter has been modified relative to the predicate by minor changes in external design and modifications of the test strip holder to support the hematocrit compensation feature. Meter software has been augmented to support the hematocrit compensation feature. The BGM009 test strip has been modified relative to the predicate by minor changes in chemistry, alteration of electrode tracks to support 6 calibration codes, and addition of electrode tracks to support the hematocrit compensation feature.
Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, test strip holder reliability testing, battery life verification, drop testing, disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, and linearity testing with validation of Lo/Hi detection, temperature and humidity testing, sample volume verification, precision testing, interferences testing, altitude testing, qualification of control solutions, hematocrit performance testing, disinfection testing with recommended disinfectant wipes was done using an animal virus test model. Results demonstrate substantial equivalence to the predicate system.
Clinical Testing	An accuracy study was conducted with home users, including evaluation of ease of use and ease of understanding of the user manual. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the BGM009 system performs in a substantially equivalent manner to that of the predicate. We

	conclude that the BGM009 system is substantially equivalent to the predicate system.